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EXAMINER

HENSON, DEVIN B

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/552,491	<b>Applicant(s)</b> MO, SEUNG-KEE	
	<b>Examiner</b> DEVIN HENSON	<b>Art Unit</b> 3736	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/6/05</u> . | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Specification***

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 4, and 15-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1 and 15, the claims recite “a control unit for verifying validity”. The claims are indefinite because it is unclear as to what validity entails and how it is verified.

Regarding claims 3 and 16, the claims recite the data detecting section “measures a dynamic pressure value in the liquid injecting lumen”, “measures a static pressure value in the bladder”, “measures the dynamic pressure in the liquid ejecting lumen”, and “measures the static pressure value in the bladder”, yielding two dynamic pressure values and two static pressure values. Claims 3 and 16 further recite “the control unit compares the dynamic pressure value and the static pressure value”, but it is unclear which of the two dynamic pressure values and which of the two static pressure values are compared by the control unit.

Regarding claims 4 and 17, the claims recite the limitation "zero point". There is insufficient antecedent basis for this limitation in the claims.

Regarding claim 18, the claim recites the limitation "any one of the dynamic pressure value and the static pressure value". There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 7-9, 11, and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Tracey (US Publication No. 2004/0133067 A1).

Regarding claim 1, Tracey discloses a urodynamics system (100) having a function of verifying bidirectional data in real time, in which urination disorder of a bladder is diagnosed in the course of filling the bladder with a liquid and ejecting a liquid from the bladder (see [0089]), the system comprising:

a bladder inserting catheter (1000) having three or more lumens inserted into the bladder through a urethra to fill the bladder with the liquid and eject the liquid from the bladder where the lumens include at least a liquid injecting lumen (1010; and see

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[0079], lines 5-7), a liquid ejecting lumen (1025), and a urethra pressure measuring lumen (1016; and see [0079], lines 8-15);

a liquid distributing section (1012) for distributing the liquid into at least any one of the liquid injecting lumen and the urethra pressure measuring lumen (see [0070], lines 11-17);

a pumping section (118) having a tube, a pump and a motor (see [0055], lines 1-4), for supplying the liquid to the liquid distributing section (see [0070], lines 11-17);

a data detecting section (128) provided between the bladder inserting catheter and the liquid distributing section, for detecting pressure data measured using the respective lumens of the bladder inserting catheter, wherein the data detecting section has pressure sensors connected to the corresponding lumens (see [0070], lines 24-46 and [0076]); and

a control unit (102) for verifying the validity of the pressure data detected by the data detecting section, and controlling the pumping section and the data detecting section in accordance with a results of the validity verification or an instruction input by a user (see [0059] and [0060]).

Regarding claim 7, Tracey discloses a flow rate adjusting section (116) provided at a front stage of the pumping section, for supplying a small amount of the liquid to the pumping section, in order to measure a urethra pressure using the urethra pressure measuring lumen (see [0012], [0014], [0059], [0060], and [0063]).

Regarding claim 8, Tracey discloses a mono-carrier connected to the bladder inserting catheter, for inserting or pulling out the bladder inserting catheter through the urethra at a constant speed (see [0007], lines 9-13).

Regarding claim 9, Tracey discloses a flow rate measuring section (2400) for measuring an amount of residual urine or physiological salt solution ejected from the bladder when the residual urine in the bladder or physiological salt solution filling in the bladder is ejected through the liquid ejecting lumen (see [0066], lines 5-10 and [0104]).

Regarding claim 11, Tracey discloses a method of verifying in real time bidirectional data in an urodynamics system (100) for diagnosing urination disorder of a bladder in the course of filling the bladder with a liquid and ejecting the liquid from the bladder (see [0089]), the urodynamics system comprising a bladder inserting catheter (1000), a data detecting section (128) and a control unit (102), the data detecting section having one or more pressure sensors (1024, 1030), the method comprising:

- a step of filling the bladder with the liquid through a liquid injecting lumen of the bladder inserting catheter inserted into the bladder through an urethra (see [0079]), the bladder inserting catheter having at least the liquid injecting lumen (1010), a liquid ejecting lumen (1025) and an urethra pressure measuring lumen (1016);

- a step in which a first pressure sensor (1024) connected to the liquid injecting lumen measures a dynamic pressure value in the liquid injecting lumen and transmits the dynamic pressure value to the control unit, in the course of filling the bladder with the liquid (see [0076], lines 12-17 and [0079]);

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a step in which a second pressure sensor (1030) connected to the liquid ejecting lumen measures a static pressure value in the bladder and transmits the static pressure value to the control unit, in the course of filling the bladder with the liquid (see [0073], lines 6-14);

a step in which the control unit compares the dynamic pressure value with the static pressure value to verify validity of the measured pressure value (see [0079], lines 13-15); and

a step of displaying a result of the validity verification in a display section (110; and see [0079], lines 15-16). The examiner notes that the urodynamics system of Tracey continuously measures pressure in all three lumens (see [0080], lines 9-11), so the first pressure sensor will measure a dynamic pressure value when liquid is in the liquid injecting lumen and a static pressure value when liquid is in the liquid ejecting lumen while the second pressure sensor will measure a static pressure value when liquid is in the liquid injecting lumen and a dynamic pressure value when the liquid is in the liquid ejecting lumen.

Regarding claim 15, Tracey discloses a defecation disorder diagnosing apparatus (100) having a function of verifying bidirectional data in real time, in which defecation disorder in the course of filling the rectum with a liquid and ejecting the liquid from the rectum, the apparatus comprising:

a rectum inserting catheter (1000) having three or more lumens inserted into the rectum through an anus to fill the rectum with the liquid and eject the liquid from the rectum where the lumens include at least a liquid injecting lumen (1010; and see [0079],

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lines 5-7), a liquid ejecting lumen (1025), and a urethra pressure measuring lumen (1016; and see [0079], lines 8-15);

a liquid distributing section (1012) for distributing the liquid into at least any one of the liquid injecting lumen and the urethra pressure measuring lumen (see [0070], lines 11-17);

a pumping section (118) having a tube, a pump and a motor (see [0055], lines 1-4), for supplying the liquid to the liquid distributing section (see [0070], lines 11-17);

a data detecting section (128) provided between the rectum inserting catheter and the liquid distributing section, for detecting pressure data measured using the respective lumens of the bladder inserting catheter, wherein the data detecting section has pressure sensors connected to the corresponding lumens (see [0070], lines 24-46 and [0076; and

a control unit (102) for verifying the validity of the pressure data detected by the data detecting section, and controlling the pumping section and the data detecting section in accordance with a results of the validity verification or an instruction input by a user (see [0059] and [0060]).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the



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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2-4, 12, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tracey (US Publication No. 2004/0133067 A1) in view of Sugrue et al. (US Patent No. 7,381,190 B2).

Regarding claim 2, it is noted that Tracey does not specifically teach the liquid is a physiological salt solution for scrub disinfection. However, Sugrue et al. discloses the liquid is a physiological salt solution for scrub or disinfection (see col. 3, lines 53-50). Hence, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the urodynamics system of Tracey to include a liquid that is a physiological salt solution, as disclosed in Sugrue et al., because saline is a common injection fluid for urodynamic catheters.

Regarding claim 3, Tracey discloses in the course of filling the bladder with the liquid through the liquid injecting lumen, the data detecting section measures a dynamic pressure value in the liquid injecting lumen using a first pressure sensor (1024) connected to the liquid injecting lumen (see [0076], lines 12-17 and [0079]), measures a

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static pressure value in the bladder using a second pressure sensor (1030) connected to the liquid ejecting lumen (see [0073], lines 6-11), and supplies the dynamic pressure value and the static pressure value to the control unit (see [0073], lines 11-14 and [0079], lines 13-16),

the data detecting section measures the dynamic pressure value in the liquid ejecting lumen using the second pressure sensor connected to the liquid ejecting lumen (see [0073], lines 6-11), measures the static pressure value in the bladder using the first pressure sensor connected to the liquid injecting lumen (see [0076], lines 12-17 and [0079]), and supplies the dynamic pressure value and the static pressure value to the control unit (see [0073], lines 11-14 and [0079], lines 13-16),

wherein the control unit compares the dynamic pressure value and the static pressure value to verify the validity of the measured data (see [0059] and [0060]).

The examiner notes that the urodynamics system of Tracey continuously measures pressure in all three lumens (see [0080], lines 9-11), so the first pressure sensor will measure a dynamic pressure value when liquid is in the liquid injecting lumen and a static pressure value when liquid is in the liquid ejecting lumen while the second pressure sensor will measure a static pressure value when liquid is in the liquid injecting lumen and a dynamic pressure value when the liquid is in the liquid ejecting lumen.

It is noted that Tracey does not specifically teach ejecting the liquid filling in the bladder through the liquid ejecting lumen. However, Sugrue et al. discloses a liquid ejecting lumen (125) that ejects liquid filling in the bladder (see col. 3, line 53). Hence, it

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would have been obvious to one of ordinary skill in the art at the time of invention to modify the urodynamics system of Tracey to include a liquid ejecting lumen that ejects liquid filling in the bladder, as disclosed in Sugrue et al., so as to drain urine from the catheter (see Sugrue et al.: col. 3, lines 50-53).

Regarding claim 4, Tracey discloses the data detecting section comprises a liquid injection section (116; and see [0055]), for injecting a liquid equal to the liquid for adjustment of a zero point when the zero points of the first pressure sensor and the second pressure sensor are not equal to each other (see [0063]). The examiner notes that the control unit controls the pump, the liquid injection section, and the pressure sensors, and thus can prime (zero) the liquid injection section when the pressure sensors are not equal.

Regarding claim 12, Tracey discloses a step in which the first pressure sensor connected to the liquid injecting lumen measures the static pressure value in the bladder and transmits the static pressure value to the control unit (see [0076], lines 12-17 and [0079]);

a step in which the second pressure sensor connected to the liquid ejecting lumen measures the dynamic pressure value in the liquid ejecting lumen and transmits the dynamic pressure value to the control unit (see [0073], lines 6-14);

a step in which the control unit compares the dynamic pressure value with the static pressure value to verify validity of the measured pressure value (see [0079], lines 13-15); and

a step of displaying a result of the validity verification in a display section (110; and see [0079], lines 15-16). The examiner notes that the urodynamics system of Tracey continuously measures pressure in all three lumens (see [0080], lines 9-11), so the first pressure sensor will measure a dynamic pressure value when liquid is in the liquid injecting lumen and a static pressure value when liquid is in the liquid ejecting lumen while the second pressure sensor will measure a static pressure value when liquid is in the liquid injecting lumen and a dynamic pressure value when the liquid is in the liquid ejecting lumen.

It is noted that Tracey does not specifically teach the step of ejecting the liquid filling in the bladder through the liquid ejecting lumen. However, Sugrue et al. the step of ejecting the liquid filling in the bladder through the liquid ejecting lumen (125; and see col. 3, line 53). Hence, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Tracey to include a ejecting liquid filling in the bladder through the liquid ejecting lumen, as disclosed in Sugrue et al., so as to drain urine from the catheter (see Sugrue et al.: col. 3, lines 50-53).

Regarding claim 16, Tracey discloses in the course of filling the rectum with the liquid through the liquid injecting lumen, the data detecting section measures a dynamic pressure value in the liquid injecting lumen using a first pressure sensor (1024) connected to the liquid injecting lumen (see [0076], lines 12-17 and [0079]), measures a static pressure value in the rectum using a second pressure sensor (1030) connected to the liquid ejecting lumen (see [0073], lines 6-11), and supplies the dynamic pressure

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value and the static pressure value to the control unit (see [0073], lines 11-14 and [0079], lines 13-16),

the data detecting section measures the dynamic pressure value in the liquid ejecting lumen using the second pressure sensor connected to the liquid ejecting lumen (see [0073], lines 6-11), measures the static pressure value in the rectum using the first pressure sensor connected to the liquid injecting lumen (see [0076], lines 12-17 and [0079]), and supplies the dynamic pressure value and the static pressure value to the control unit (see [0073], lines 11-14 and [0079], lines 13-16),

wherein the control unit compares the dynamic pressure value and the static pressure value to verify the validity of the measured data (see [0059] and [0060]).

The examiner notes that the defecation disorder diagnosing apparatus of Tracey continuously measures pressure in all three lumens (see [0080], lines 9-11), so the first pressure sensor will measure a dynamic pressure value when liquid is in the liquid injecting lumen and a static pressure value when liquid is in the liquid ejecting lumen while the second pressure sensor will measure a static pressure value when liquid is in the liquid injecting lumen and a dynamic pressure value when the liquid is in the liquid ejecting lumen.

It is noted that Tracey does not specifically teach ejecting the liquid through the liquid ejecting lumen. However, Sugrue et al. discloses a liquid ejecting lumen (125) that ejects liquid (see col. 3, line 53). Hence, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the urodynamics system of Tracey to

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include a liquid ejecting lumen that ejects liquid, as disclosed in Sugrue et al., so as to drain liquid from the catheter.

Regarding claim 17, Tracey discloses the data detecting section comprises a liquid injection section (116; and see [0055]), for injecting a liquid equal to the liquid for adjustment of a zero point when the zero points of the first pressure sensor and the second pressure sensor are not equal to each other (see [0063]). The examiner notes that the control unit controls the pump, the liquid injection section, and the pressure sensors, and thus can prime (zero) the liquid injection section when the pressure sensors are not equal.

Claims 5, 6, 13, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tracey (US Publication No. 2004/0133067 A1) in view of Rao (US Patent No. 5,924,984).

Regarding claim 5, Tracey discloses a rectum inserting catheter (1702) which is inserted into a rectum through the anus for measuring rectum pressure (see [0097] and [0100], lines 2-5),

wherein the data detecting section is provided between the rectum inserting catheter and the liquid distributing section, and further detects pressure data measured by the rectum inserting catheter (see [0097] and [0100], lines 11-18). It is noted that Tracey does not specifically teach the rectum inserting catheter is coupled to a sealed balloon and the liquid distributing section distributes liquid into the rectum inserting catheter. However, Rao discloses the rectum inserting catheter (50) is coupled to a

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sealed balloon (66) and the liquid distributing section (72) distributes liquid into the rectum inserting catheter (see col. 3, lines 2-9 and col. 4, lines 57-65). Hence, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the rectum inserting catheter of Tracey to be coupled with a sealed balloon and receive liquid, as disclosed in Rao so as to subtract abdominal (rectal) pressure from the bladder pressure to calculate detrusor pressure (see Tracey: [0101]).

Regarding claim 6, it is noted that Tracey does not specifically teach an abdominal electromyogram electrode. However, Rao discloses an abdominal electromyogram electrode (82) to be attached to a human body, as a biological signal measuring electrode for detecting the influence which a force applied to an abdomen in urination gives to a urination system,

wherein the control unit (30) compares a pressure value corresponding to a voltage value measured using the abdominal electromyogram electrode with the rectum pressure measured using the rectum inserting catheter, and verifies validity of the measured data (see col. 4, lines 38-54). Hence, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the rectum inserting catheter of Tracey to include an abdominal electromyogram electrode, as disclosed in Rao so as to monitor both pressure and electrical activity of the anal sphincter (see Rao: col. 2, lines 2-9).

Regarding claim 13, Tracey discloses the urodynamics system further comprises a rectum inserting catheter (1702) which is inserted into a rectum through an anus for measuring a rectum pressure (see [0097] and [0100], lines 2-5),

the method further comprising:

a step in which a third pressure sensor connected to the rectum inserting catheter inserted through the anus measures the rectum pressure and transmits the rectum pressure to the control unit (see [0097] and [0100]); and

a step of displaying the result of the validity verification in a display section (110; and see [0100], lines 15-18).

It is noted that Tracey does not specifically teach the rectum inserting catheter is coupled to a sealed balloon. Further, Tracey does not specifically teach an abdominal electromyogram electrode. However, Rao discloses the rectum inserting catheter (50) is coupled to a sealed balloon (66) and an abdominal electromyogram electrode (82) to be attached to a human body, as a biological signal measuring electrode for detecting the influence which a force applied to an abdomen in urination gives to a urination system. Rao further discloses a step in which the control unit (30) in Rao) compares a pressure value corresponding to a voltage value measured using the abdominal electromyogram electrode with the rectum pressure (see col. 4, lines 17-19) to verify validity of the measured data (see col. 4, lines 38-46); and

a step of displaying the result of the validity verification in a display section (see col. 4, lines 46-54). Hence, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Tracey to include a rectum inserting



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catheter coupled to a sealed balloon and an abdominal electromyogram electrode to compare abdominal pressure measurements, as disclosed in Rao, so as to subtract abdominal (rectal) pressure from the bladder pressure to calculate detrusor pressure (see Tracey: [0101]) and monitor both pressure and electrical activity of the anal sphincter (see Rao: col. 2, lines 2-9).

Regarding claim 18, it is noted that Tracey does not specifically teach an abdominal electromyogram electrode. However, Rao discloses an abdominal electromyogram electrode (82) to be attached to a human body, as a biological signal measuring electrode for detecting the influence which a force applied to an abdomen in defecation gives to a defecation system,

wherein the control unit (30) compares a pressure value corresponding to a voltage value measured using the abdominal electromyogram electrode with any one of the dynamic pressure value and the static pressure value measured using the rectum inserting catheter, to verify the validity of the measured data (see col. 4, lines 38-54). Hence, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the rectum inserting catheter of Tracey to include an abdominal electromyogram electrode, as disclosed in Rao so as to monitor both pressure and electrical activity of the anal sphincter (see Rao: col. 2, lines 2-9).

Claims 10 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tracey (US Publication No. 2004/0133067 A1) in view of Baker (US Patent No. 5,957,920).

Regarding claim 10, it is noted that Tracey does not specifically teach a residual urine detecting section comprising a first electrode and a second electrode for measuring impedance through the bladder. However, Baker discloses a residual urine detecting section (80) in which a current flowing through a first electrode (70), the bladder and a second electrode (72) flows,

wherein the control unit (90, 100, 115) calculates the amount of residual urine in the bladder using a magnitude of the current flowing through the first electrode, the bladder and the second electrode and an impedance value calculated from a potential difference between the first electrode and the second electrode (see col. 10, lines 31-59 and col. 11, lines 40-50), and compares the amount of residual urine with a flow rate measured by the flow rate measuring section to verify the validity of the measured data. The examiner notes that control units of Tracey and Baker are both microprocessors, so the combination of the two references yields one microprocessor that receives flow rate measurements (as disclosed by Tracey with regard to claim 9) and residual urine impedance measurements (as disclosed by Baker) and compares the obtained measurements to verify the validity. Hence, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the urodynamics system of Tracey to include a residual urine detecting section, as disclosed in Baker, as both devices are catheters for assessing urinary incontinence (see Tracey: [0002] and Baker: col. 1, lines 17-20).

Regarding claim 14, Tracey discloses the urodynamics system further comprises a flow rate measuring section (2400) for measuring an amount of residual urine or

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physiological salt solution ejected from the bladder when the residual urine in the bladder or the physiological salt solution filling in the bladder is ejected through the liquid ejecting lumen (see [0066], lines 5-10 and [0104]). It is noted that Tracey does not specifically teach a residual urine detecting section comprising a first electrode and a second electrode for measuring impedance through the bladder. However, Baker discloses a residual urine detecting section (80) in which a current flows through a first electrode (70), the bladder and a second electrode (72),

a step in which the control unit (90, 100, 115) calculates the amount of residual urine in the bladder using a magnitude of the current flowing through the first electrode, the bladder and the second electrode and an impedance value calculated from a potential difference between the first electrode and the second electrode (see col. 10, lines 31-59 and col. 11, lines 40-50);

a step in which the control unit compares the amount of residual urine with a flow rate measured by the flow rate measuring section to verify validity of the measured data. The examiner notes that control units of Tracey and Baker are both microprocessors, so the combination of the two references yields one microprocessor that receives flow rate measurements (as disclosed by Tracey with regard to claim 9) and residual urine impedance measurements (as disclosed by Baker) and compares the obtained measurements to verify the validity.

a step of displaying a result of the validity verification in a display section (see col. 11, lines 40-50). Hence, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the method of Tracey to include a residual urine

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detecting section for comparing with the flow rate measuring section, as disclosed in Baker, as both methods assess urinary incontinence (see Tracey: [0002] and Baker: col. 1, lines 17-20).

### ***Double Patenting***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Applicant is advised that should claims 1, 3, 4, and 6 be found allowable, claims 15-18 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). See applicant's specification (p. 43, line 13-p. 44, line 8).

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

McRae (US Patent No. 5,823,972) discloses a bladder pressure and urinary flow measurement apparatus.

Wallace et al. (US Patent No. 6,447,462 B1) discloses a urodynamic catheter with a balloon that measured bladder and rectal pressure.

Dijkman (US Publication No. 2003/0167022 A1) discloses a multi-lumen catheter for measuring pressure and detecting residual urine.

Stoehrer et al. (US Publication No. 2005/0038328 A1) discloses a device for examining dysfunction of the bladder that measures bladder, urethra, and rectum pressure and abdominal muscle tension.

Cohen et al. (US Publication No. 2005/0216069 A1) discloses a pelvic disorder treatment device with a pressure sensor, an electromyogram electrode, and an impedance sensor.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEVIN HENSON whose telephone number is (571)270-5340. The examiner can normally be reached on M-TH 7-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3736

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. H./  
Examiner, Art Unit 3736  
3/10/10

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736

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